



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 21 1986

MEMORANDUM

SUBJECT: EPA Registration No. 464-448 - Chlorpyrifos
on Tobacco; Response to Letter from Dow Chemical
Company, RCB No. 882

FROM: Charles Frick, DABFT, Chemist *C. Frick 7/21/86*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Larry Schnaubelt/D. Edwards, PM Team 12
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

THRU: Andrew Rathman, Section Head
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *ARR*

Dow Chemical has previously filed for an amended registration of Lorsban 4E (EPA Registration No. 464-448), see memorandum, Leung Cheng, January 9, 1985) used as a preplant insecticide/nematicide on tobacco. The current registered use calls for a single preplant application of 2 to 3 lb ai/A, applied broadcast and incorporated to a depth of 2 to 4 inches. The company wishes to add a use to control low to moderate infestations of nematodes. For this purpose chlorpyrifos is to be used at the rate of 4 to 5 lb ai/A preplant with incorporation to 4 inches or more. Nemacur® 3 is to be used in combination (tank mix) at the rate of 4 quarts per acre. It was noted in the L. Cheng memorandum that the sole restriction of "Do not make more than one application per season" has been deleted; as the Dow letter makes no comment on this deletion we must assume this restriction has not been reincorporated into the Lorsban labeling.

Tolerances have been established for combined residues of chlorpyrifos [O,O-diethyl-O-(3,5,6-trichloro-2-pyridyl) phosphorothioate] and its metabolite 3,5,6-trichloro-2-pyridinol in or on numerous commodities including whole milk at 0.02 ppm, eggs at 0.1 ppm, and meat at 0.5 to 2.0 ppm [40 CFR 180.342].

Included in the previous submission were two reports entitled, "Determination of Chlorpyrifos and 3,5,6-Trichloro-2-pyridinol in Green and Cured Tobacco Grown in Soil Treated with Lorsban Insecticides" and "Determination of Residues in Smoke from Tobacco Treated with Chlorpyrifos." Also submitted and reviewed were residue data, analytical methods for determining chlorpyrifos and its pyridinol metabolite, and sample chromatograms (see memorandums of L. Bradley, June 18, 1980 and E. Zager, March 2, 1983, EPA Registration Nos. 464-448 and 464-523).

Residue Chemistry Branch (RCB) recommended against this amended registration (memorandum of L. Cheng, January 9, 1985) and requested the company to perform additional pyrolysis studies on chlorpyrifos according to the Residue Chemistry Guidelines and that use be limited to one application per season and that the label be so revised.

In response to the RCB recommendation, a letter from the Dow Chemical Company dated March 26, 1986 is, in part, as follows:

. . . the Agency requested that pyrolysis studies be conducted on cured tobacco which has been fortified with suitable levels of chlorpyrifos and its 3,5,6-trichloro-2-pyridinol metabolite to support the increase in dosage rate for use of chlorpyrifos on tobacco. The basis for this request was a previously submitted study by R.L. McKellar entitled "Determination of Chlorpyrifos and 3,5,6-Trichloro-2-pyridinol in Green and Cured Tobacco Grown in Soil Treated with LORSBAN Insecticides" (MRID 00030504). In this study residue data are shown for LORSBAN 4E or LORSBAN 15G applied as a soil treatment to tobacco at the rate of 2 to 3 lb of chlorpyrifos per acre. Residue data reported for both green and cured tobacco were comparable for each formulation. For the green leaves, a residue level of < 0.05 ppm (gross value of < 0.01 ppm) was shown for the pyridinol metabolite while residues of chlorpyrifos were non-detectable based on detection limits of 0.05 ppm and 0.01 ppm for the pyridinol metabolite and chlorpyrifos, respectively. In the cured tobacco samples, residue levels of non-detectable to 0.01 ppm were reported for chlorpyrifos while those for the pyridinol metabolite were observed between 0.05 to 0.11 ppm. The approximately 10X higher levels observed in the cured leaves can be accounted for through the approximately 75% weight loss in the leaves which occurs through water loss in the curing process.

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In view of the above cited data, we would appreciate a clarification of the requirement to conduct a smoking study Under section 171-11 of the Pesticide Assessment Guidelines, Subdivision O (1982), pyrolysis studies with tobacco are required only if residues on green freshly-harvested tobacco exceed 0.1 ppm Finally, if pyrolysis studies are required, it would seem that a study with chlorpyrifos is not appropriate because residue levels of this active ingredient were no more than 0.01 ppm in cured tobacco which represents a potentially more concentrated situation than a green tissue sample

RCB Response

As the Dow letter states, under section 171-11 of the Pesticide Assessment Guidelines, Subdivision O (1982), pyrolysis studies with tobacco are required if residues on green freshly-harvested tobacco exceed 0.1 ppm. Section 171-11 of the Pesticide Assessment Guidelines was promulgated without the following paragraph: "(2) Total residue on cured or dried tobacco. If residues at 0.1 ppm or more are detected, the determinations of the next paragraph of this section are required." The next paragraph requires pyrolysis products to be characterized and quantified. A copy of the modified section 171-11, attached to this memorandum, should be supplied to Dow Chemical Company. The logic of this requirement is well stated in the Dow Chemical Company letter: ". . . cured tobacco which represents a potentially more concentrated situation than a green tissue sample."

As previously noted, in the cured tobacco samples, residue levels of nondetected to 0.01 ppm were reported for chlorpyrifos while those for the pyridinol metabolite were between 0.05 to 0.11 ppm. These data indicate that the residue of concern is the pyridinol metabolite of chlorpyrifos; as under this amendment request the residues of this metabolite could reach a level of 0.22 ppm. RCB agrees with the Dow Chemical Company contention that the pyrolysis profile studies should be conducted with the pyridinol metabolite of chlorpyrifos.

Conclusions

For a favorable recommendation of this requested amended use of chlorpyrifos on tobacco, pyrolysis studies must be

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conducted on the pyridinol metabolite of chlorpyrifos. Additionally, the use must be limited to one application per season and the label should be so revised.

Attachment: Sec. 171-11 to all ccs and addressees

cc: R.F., Amend Use F., S.F., Reviewer, PMSD/ISB
RDI ARR 7/15/86:RDS 7/16/86
88039:Frick:C.Disk:KENCO:7/17/86:TAR:VO

§171-11 Tobacco Uses.

Use of a pesticide on tobacco does not require a tolerance or an exemption from the requirement to obtain a tolerance. Nonetheless, data are needed to assess the exposure of man to the residue remaining at the time of use of the tobacco. The data required include a residue profile for the tobacco and its smoke.

This residue profile must include the active ingredient and all significant plant metabolites of the active ingredient, translocated degradation products from soil, and photodegradation products. Radioisotopic techniques will normally be required to identify the significant components of the residue. If residues at 0.1 ppm or more are detected, analytical methods must be developed.

Data from the following studies must be submitted to show conclusively the level of residue likely to result from the use of the pesticide:

- (1) Total residues on green freshly-harvested tobacco. If residues at 0.1 ppm or more are detected, the determinations of the next paragraph of this section are required.
- (2) Total residues on cured or dried tobacco. If residues at 0.1 ppm or more are detected, the determinations in the next paragraph are required.
- (3) Pyrolysis products derived from the active ingredient must be characterized and the level of residue in smoke must be quantified.